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New Drug Application (NDA): 022460

Company: GLAXOSMITHKLINE

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- [Other Important Information from FDA \(http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm258424.htm\)](http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm258424.htm)
- [Summary Review \(http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022460Orig1s000SumR.pdf\)](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022460Orig1s000SumR.pdf)

Products on NDA 022460

CSV Excel Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
JALYN	DUTASTERIDE; TAMSULOSIN HYDROCHLORIDE	0.5MG;0.4MG	CAPSULE;ORAL	Prescription	AB	Yes	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 022460**Original Approvals or Tentative Approvals**

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert
06/14/2010	ORIG-1	Approval	Type 4 - New Combination	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022460s000lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2010/022460s000ltr.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2010/022460s000TA.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022460s000_jalyn_toc.cfm) Summary Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022460s000_summary_review.pdf)

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Supplements

CSV	Excel	Print			
Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note	
11/01/2017	SUPPL-8	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022460s007s008lbl.pdf)		
11/01/2017	SUPPL-7	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022460s007s008lbl.pdf)		
06/13/2016	SUPPL-9	Manufacturing (CMC)		Label is not available on this site.	
04/25/2013	SUPPL-5	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022460s003s004s005lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/022460Orig1s003,s004,s005ltr.pdf)		
04/25/2013	SUPPL-4	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022460s003s004s005lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/022460Orig1s003,s004,s005ltr.pdf)		
04/25/2013	SUPPL-3	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022460s003s004s005lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/022460Orig1s003,s004,s005ltr.pdf)		
06/27/2012	SUPPL-2	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022460s002lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/022460s002ltr.pdf)		
06/09/2011	SUPPL-1	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022460s001lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/022460s001ltr.pdf)		

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Labels for NDA 022460



Therapeutic Equivalents for NDA 022460

